



**EXPRESS MAIL NO.: EV 475 141 816 US**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Ensoli	Confirmation No.:	9400
Application No.:	09/555,534	Art Unit:	1648
Filed:	May 31, 2000	Examiner:	Stucker, Jeffrey J.
For:	HIV TAT, OR DERIVATIVES THEREOF FOR PROPHYLACTIC AND THERAPEUTIC VACCINATION		
		Attorney Docket No.:	11340-003-999

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the continuing duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the United States Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application which are or may be related to patentability of any claim of the application, Applicant hereby directs the Examiner's attention to references C01-C13 listed on the accompanying List of References Cited by Applicant (revised Form PTO-1449). A copy of references C01-C13 is submitted herewith.


Identification of the listed references is not to be construed as an admission of Applicant that such references are available as "prior art" against the subject application.

Applicant respectfully requests that the Examiner review the listed references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(c), since this Supplemental Information Disclosure Statement is being filed after the mailing date of a first Office Action on the merits, it is estimated that a fee of **\$180.00** is due for this submission. Please charge the required fee to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed for accounting purposes.

Respectfully submitted,

Date: December 13, 2005

 32.605  
Adriane M. Antler (Reg. No.)  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, New York 10017  
(212) 326-3939

Enclosure

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)



ATTY. DOCKET NO.

11340-003-999

APPLICATION NO.

09/555,534

APPLICANT

Ensoli

FILING DATE

May 31, 2000

GROUP

1648

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	Ahmed <i>et al.</i> , Studies on the mechanism of acetonitrile toxicity. I: Whole body autoradiographic distribution and macromolecular interaction of 2-14C-acetonitrile in mice. <i>Pharmacol Toxicol.</i> 1992 May;70(5 Pt 1):322-30.
C02	Bohan <i>et al.</i> , Analysis of Tat transactivation of human immunodeficiency virus transcription in vitro. <i>Gene Expr.</i> 1992;2(4):391-407.
C03	Michael E. Byrnes, <i>Methods in Molecular Biology</i> , Vol. 32: Basic Protein and Peptide Protocols, Chapter 4, page 42, Edited by B.M. Dunn and M.W. Pennington, 1994, Humana Press Inc.
C04	Ensoli <i>et al.</i> , Release, uptake, and effects of extracellular human immunodeficiency virus type I Tat protein on cell growth and viral transactivation. <i>J Virol.</i> 1993 Jan;67(1):277-87.
C05	Gomez-Cambronero <i>et al.</i> , Actions of the protease inhibitor phenylmethylsulfonyl fluoride on neutrophil granule enzyme secretion and superoxide production induced by fMet-Leu-Phe and phorbol 12-myristate-13-acetate. <i>Int Arch Allergy Appl Immunol.</i> 1989;89(4):362-8.
C06	Jan-Chister Janson and Lars Rydén in <i>Protein Purification</i> , Chapter 1, pages 16-18, Edited by VCH Publishers Inc., 1989
C07	Lotti <i>et al.</i> , Promotion of organophosphate-induced delayed polyneuropathy by phenylmethanesulfonyl fluoride. <i>Toxicol Appl Pharmacol.</i> 1991 Apr;108(2):234-41.
C08	Massicotte <i>et al.</i> , Neuropathologic effects of phenylmethylsulfonyl fluoride (PMSF)-induced promotion and protection in organophosphorus ester-induced delayed neuropathy (OPIDN) in hens. <i>Neurotoxicology.</i> 1999 Oct;20(5):749-59.
C09	Robles <i>et al.</i> , 2005, Acetonitrile, in <i>Encyclopedia of Toxicology, Second Edition</i> , (Wexler, ed.) Elsevier, Philadelphia, PA, pp. 28-30
C10	Paul C. Sadek, <i>The HPLC Solvent Guide</i> , Chapter 7, Section 7.6.4 on page 251, 1996, John Wiley & Sons, Inc.
C11	Chris Shaw, <i>Methods in Molecular Biology</i> , Vol. 32: Basic Protein and Peptide Protocols, Chapter 31, page 275, 6 <sup>th</sup> sentence under Introduction, Edited by J.M. Walker, 1994, Humana Press Inc.
C12	Toxsys database Record No. AL7700000 for Acetonitrile
C13	Toxsys database Record No. AJ9625000 for Acetic acid, trifluoro

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT:** ENSOLI **EXAMINER:**  
**SERIAL NO.:** 09/555,534 **ART UNIT:** 1644

**FILED:** May 31, 2000

**FOR:** HIV-1 TAT, OR DERIVATIVES  
THEREOF FOR PROPHYLACTIC  
AND THERAPEUTIC VACCINATION

November 17, 2000

VIA HAND DELIVERY

**INFORMATION DISCLOSURE STATEMENT**

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

This Information Disclosure Statement (hereinafter sometimes referred to as "IDS") is submitted in accordance with 37 C.F.R. §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. §1.97, as it is filed:

(Check one of the boxes opposite A-D)

☐ A. within three months of the filing date of the above-identified national application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in the above-identified international application.

☒ B. before the mailing date of a first office action on the merits.

☐ C. after the times set forth in (A) and (B) above, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a notice of allowance under 37 C.F.R. §1.311, and the necessary statement pursuant to 37 C.F.R. §1.97(e) appears below (see box "i") or the necessary fee is enclosed (see box "ii" below).

(check one of the boxes opposite "i" or "ii" below)

☐ i. (check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

☐ ii. A check for the fee set forth in 37 C.F.R. §1.17(p), presently believed to be \$ 240.00, is enclosed.

☐ D. after the times set forth in (A), (B), and (C) above, but before payment of the issue fee, since Applicant petitions for the consideration of this Information Disclosure Statement by a petition enclosed herewith pursuant to 37 C.F.R. §1.97(d)(2), a check for the petition fee set forth in 37 C.F.R. §1.17(i), presently believed to be \$ 130.00, is enclosed, and the necessary statement pursuant to 37 C.F.R. §1.97(e) appears below:

(check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this

Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

2. In accordance with 37 C.F.R. §1.98(a)(1), this IDS includes a list on form PTO-1449 of all patents, publications, or other information submitted for consideration by the Office, incorporated into this IDS as an attachment hereto. Pursuant to 37 C.F.R. §1.98(b): (i) each U.S. patent listed is identified by patentee, patent number, and issue date; (ii) each foreign patent or published foreign patent application is identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application; and (iii) each publication is identified by author (if any), title, relevant pages of the publication, date, and place of publication. A legible copy of each document listed is attached and incorporated into this IDS, except that no copy of any U.S. patent application is included pursuant to 37 C.F.R. §1.98(a)(2)(iii) and except as explained below.

(check the boxes opposite A and/or B and fill in blanks, if appropriate)

☐ A. Document(s) \_\_\_\_\_ is (are) substantively cumulative to document(s) \_\_\_\_\_, and, in accordance with 37 C.F.R. §1.98(c), only a copy of each of the latter document(s) is (are) attached.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon for an earlier filing date under 35 U.S.C. §120:

[insert serial numbers and filing dates of prior applications]

These documents are identified by attaching hereto copies of the forms PTO-892 and/or PTO-1449 from the files of the prior application(s) and Applicant requests that they be considered and made of record in this application in accordance with 37 C.F.R. §1.98(d). Pursuant to 37 C.F.R. §1.98(d), copies of these documents need not be provided with this IDS.

(check paragraphs 3 and/or 4, if applicable)

☐ 3. Document(s) \_\_\_\_\_ is (are) not in the English language. In accordance with 37 C.F.R. §§1.98(a)(3), 1.98(c), it is stated that:

(check the applicable statement(s))

☐ English translation(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) is (are) enclosed and, thus no concise explanation of their relevance is required, (see M.P.E.P., §609, p. 600-92).

☐ English-language equivalent(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) which is (are) in fact translation(s) of the document(s) is (are) enclosed.

☐ The attached English-language version of a search report or other action by a foreign patent office in a counterpart foreign application which cites document(s) \_\_\_\_\_ and which indicates the degree of relevance found by the foreign office is submitted to satisfy the requirement for a concise explanation of the relevance of the document(s), (see M.P.E.P., §609, p. 600-93).

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

[insert concise explanation of relevance]

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on the attached sheet.

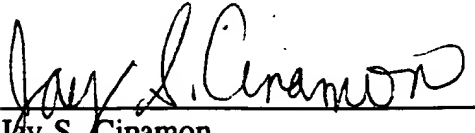
☐ 4. Other information being provided for the Examiner's consideration follows:

[insert other information]

5. In accordance with 37 C.F.R. §§1.97(g), 1.97(h), the filing of this IDS shall not be construed as a representation that a search has been made or as an admission that information cited in this IDS is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b). Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

6. Please charge any deficiency or other fees or credit any refund or overpayment to Deposit Account No. 01-0035.

Respectfully submitted,

  
Jay S. Cinamon  
Attorney for Applicant  
Registration No. 24,156

ABELMAN, FRAYNE & SCHWAB  
150 East 42nd Street  
New York, NY 10017-5612  
(212) 949-9022

notarbar\1116ens.ids



**Hon. Commissioner of Patents  
and Trademarks**  
**Date Stamp as acknowledgement  
of receipt of:**

**Applicant:** ENSOLI  
**Serial No.:** 09/555,534  
**Filed:** May 31, 2000  
**For:** HIV-1 TAT, OR  
DERIVATIVES  
THEREOF...

**Control No.:** 204,610  
**DOC. TYPE:**

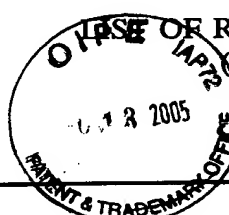
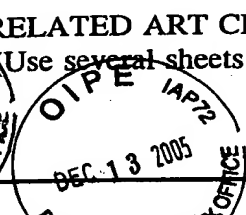
1. IDS before  
first OA;
2. PTO 1449  
citing 176  
refs.;
3. copies of  
176 cited  
refs.

**Initials:** JSC:hk  
**Date:** November 17, 2000

BY HAND DELIVERY

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RECEIVED  
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Form PTO-1449  
(Rev. 7-80)U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket Control No.  
204,610Serial No.  
09/555,534


 USE OF RELATED ART CITED BY APPLICANT  
(Use several sheets if necessary)
Applicant  
ENSOLIFiling Date  
May 31, 2000Group  
1644

## U.S. PATENT DOCUMENTS

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
AA						

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation YES NO
AL					

## OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AR		Agostini et al., Blood, Vol. 90: 1115 (1997).
AS		Albini et al., Proc. Natl Acad Sci., USA 92:4838 (1995).
AT		Allan et al., Science 230: 810 (1985).
AU		Antibodies - A Laboratory Manual, Eds., Harlow F., Lane D., Cold Spring Harbor Laboratory (1988).
AV		Arya et al., Science 229:69 (1985).
AW		Ariyoshi et al., AIDS 9:555 (1995).
AX		Audibert et al., Immunol. Today 14:281 (1993).
AY		Badolato et al., Blood 90: 2804 (1997).

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

US COMM-DC 80-3985

Form PTO-1449 (Rev. 7-80)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket Control No. 204,610	Serial No. 09/555,534
LIST OF RELATED ART CITED BY APPLICANT (Use several sheets if necessary)		Applicant ENSOLI	
		Filing Date May 31, 2000	Group 1644

## U.S. PATENT DOCUMENTS

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
AA						

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation YES NO
AL					

## OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AR		Barillari et al., J. Immunol. 149: 3727 (1992).
AS		Barillari et al., Proc. Natl Acad. Sci., USA 90: 7941 (1993).
AT		Blomberg et al., J. Immunol. Methods 160: 27-34 (1993).
AU		Blomberg, et al., J. Immunol. Methods 168: 267-273 (1994).
AV		Blomberg et al., J. Immunol. Methods 193: 199-206 (1996).
AW		Bohan et al., Gene Expr. 2:391 (1992).
AX		Bourgault et al., J. Virol. 66:750 (1992).
AY		Boyer et al., Nature Med., 3:526 (1997).

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

US COMM-DC 80-3985

Form PTO-1449 (Rev. 7-80)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket Control No. 204,610		Serial No. 09/555,534			
<b>LIST OF RELATED ART CITED BY APPLICANT</b> (Use several sheets if necessary)				Applicant ENSOLI		Filing Date May 31, 2000			
				Group 1644					
<b>U.S. PATENT DOCUMENTS</b>									
*Examiner Initial		Document Number			Date	Name	Class	Subclass	Filing Date If Appropriate
	AA								
<b>FOREIGN PATENT DOCUMENTS</b>									
		Document Number			Date	Country	Class	Subclass	Translation YES NO
	AL								
<b>OTHER RELATED ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>									
	AR		Bruisten et al., J. Infect. Dis. 166: 620 (1992).						
	AS		Buseyn et al., J. Virol. 67: 694 (1993).						
	AT		Butera et al., J. Virol. 65: 4645 (1991).						
	AU		Butera et al., J. Virol. 68: 2726 (1994).						
	AV		Cafaro et al., J. AIDS Research and Hum. Retrov. 14:65 (1997).						
	AW		Carrol et al., Science 276: 273-276 (1997).						
	AX		Carson et al., J. Clin. Invest. 99:937 (1997).						
			Chang et al., J. Biomed. Sci 2: 189 (1995).						
	AY								
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FOREIGN PATENT DOCUMENTS												
	AL	Document Number				Date	Country	Class	Subclass	Translation YES NO		
OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)												
	AR		Chang et al., AIDS 11: 1421 (1997).									
	AS		Chavany et al., Phar. Res. 9: 1370 (1994).									
	AT		Chen et al., J. Immunol. 149: 4060 (1992).									
	AU		Chiarantini et al., Vaccine 15: 276 (1997).									
	AV		Chiarantini et al., Clin. Diag. Lab Immunol. 5: 235 (1998).									
	AW		Chirmule et al., J. Virol. 69:492 (1995).									
	AX		Choppin et al., J. Immunol. 147:569 (1991).									
	AY		Corallini et al., Cancer Res. 53: 5569 (1993).									
Examiner								Date Considered				
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>												

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<b>LIST OF RELATED ART CITED BY APPLICANT</b> (Use several sheets if necessary)												Applicant <b>ENSOLI</b>			
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	AL														
<b>OTHER RELATED ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>															
	AR														
	AS		Culman et al., J. Immunol. 146: 1560 (1991).												
	AT		Couillin et al., J. Exp. Med. 180:1129 (1994).												
	AU		Danko et al., Vaccine 12: 1499 (1994).												
	AV		Di Fabio et al., Vaccine 16: 485 (1998).												
	AW		Ensoli et al., IV International Conference on AIDS, Stockholm, 3087: 241 (1988).												
	AX		Ensoli et al., Nature 345: 84 (1990).												
	AY		Ensoli et al., J. Virol. 67: 277 (1993).												
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								Filing Date May 31, 2000						Group 1644	
U.S. PATENT DOCUMENTS															
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		Document Number	Date	Country	Class	Subclass	Translation YES      NO								
	AL														
OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
	AR		Ensoli et al., Nature 371: 674 (1994).												
	AS		Ensoli et al., AIDS Updates, Eds. V. De Vita Jr., Hellman S., Rosenberg S.A., Lippincott J.B., Philadelphia; 7:1 (1994).												
	AT		Felber et al., Proc. Natl. Acad. Sci., 86: 1495 (1989).												
	AU		Fine et al., Ann. Plast. Surg. 20: 573 (1988).												
	AV		Fiorelli et al., J. Clin. Invest. 95: 1723 (1995).												
	AW		Folks et al., Science 238:800 (1987).												
	AX		Franchini et al., Virology 155: 593 (1986).												
	AY		Frankel et al., Cell 55: 1189 (1988).												
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AA						

**FOREIGN PATENT DOCUMENTS**

Document Number	Date	Country	Class	Subclass	Translation YES      NO

**OTHER RELATED ART** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

AR		Fugier-Vivier et al., J. Exp. Med. 186:813 (1997).
AS		Gait et al., Trends Biochem Sci. 18:255 (1993).
AT		Glorioso et al., Ann. Rev. Microbiol. 49: 675 (1995).
AU		Gombert et al., Virology 176: 458 (1990).
AV		Goletti et al., J. Virol. 69: 2540 (1995).
AW		Gorman et al., Mol. Cell Biol. 2:1044 (1982).
AX		Grabstein et al., Science 264: 965 (1994).
AY		Grosjean et al., J. Exp. Med. 186: 801 (1997).

Examiner

Date Considered

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Form PTO-1449  
(Rev. 7-80)U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket Control No.  
204,610Serial No.  
09/555,534LIST OF RELATED ART CITED BY APPLICANT  
(Use several sheets if necessary)

Applicant ENSOLI

Filing Date  
May 31, 2000Group  
1644

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## OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR		Guy et al., Nature 330: 266 (1987).
	AS		Harrer et al., AIDS Res. Hum. Retrov. 12:585 (1996).
	AT		Harrich et al., EMBO J. 16: 1224 (1997).
	AU		Hinkula et al., J. Virol. 71: 5528 (1997).
	AV		Haneberg et al., Infect. Immun. 62:15 (1994).
	AW		Huang et al., EMBO J. 13: 2886 (1994).
	AX		Huard et al., Gene Ther. 2: 385 (1995).
	AY		Igarashi et al., AIDS Res. Hum. Retrov. 10:1021 (1994).

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## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation YES NO
	AL						

## OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR		Januleit et al., J. Immunol. 158:2610 (1997).
	AS		Jullien et al., J. Immunol. 158: 800 (1997).
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\* O'Hagan reference is cited; however, we could not locate a hard copy. The citation could have been cited in another publication and the citation is therefore continued herein



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